



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 24 2000

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Mr. Lawrence Tabak
President
Tabak's Health Products
3198-G Airport Loop Drive
Costa Mesa, California 92626

Dear Mr. Tabak:

This is in response to your letter to the Food and Drug Administration (FDA) dated October 10, 2000. In your letter, you asked us to explain the basis for our position, stated in a letter to you dated September 20, 2000, that the statement "helps maintain normal blood sugar levels" is not a claim that may be made for dietary supplements pursuant to 21 U.S.C. 343(r)(6).

In our May 22, 2000 letter, we stated that the claim "...help maintain normal blood sugar levels" would not be an appropriate structure/function claim under 21 U.S.C. 343(r)(6). In the preamble to the January 6, 2000 final rule (see 65 FR 1000), FDA stated that health maintenance claims that do not imply disease treatment or prevention would be acceptable structure function claims. We stated that if the health maintenance claim did not use terms that are so closely identified with a specific disease or that so clearly referred to a particular at-risk population, we believed that such a claim could be a structure/function claim under 21 U.S.C. 343(r)(6) (see discussion at 65 FR 1018).

You stated in your letter that you believe that the claim "...help maintain normal blood sugar levels" is an appropriate structure/function claim that does not imply disease treatment, prevention, or mitigation because we stated in the preamble to the final rule that a claim such as "use as part of your diet to help maintain a healthy blood sugar level" would be an acceptable structure/function claim. We disagree. We believe that any claim that a product is intended to maintain normal blood glucose levels is an implied disease claim. This conclusion is based on the fact that a claim about external intervention to affect blood glucose levels is implicitly a claim to correct a defect in blood glucose levels because it is not necessary to improve, modify, or otherwise affect blood glucose unless it is impaired.

However, a claim that a product is important or plays a role in the maintenance or regulation of blood glucose that is already normal or within normal limits could be an appropriate structure/function claim, depending on the context. As we discussed in the preamble to the final rule, the context in which a particular claim is made is important in determining whether

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a claim may be a disease claim or a structure/function claim. Consequently, if the context of a claim about a product intended to affect blood glucose clearly and unambiguously makes clear that the product is not intended to have an affect on abnormal blood glucose (for example, the claim in the preamble of the January 6, 2000 final rule which you cited in your letter), then such a claim may be an acceptable structure/function claims under 21 U.S.C. 343(r)(6). But, the claim you are making for your product contains no such context and, consequently, is not an acceptable structure/function claim under 21 U.S.C. 343(r)(6).

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-811 (r/f, file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Betz)

GCF-1 (Nickerson, Dorsey)

f/t:rjm:HFS-811:10/18/00:tabak.adv:disc51

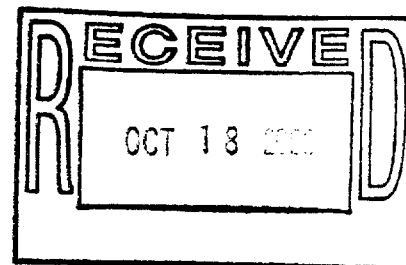
*Exceptional
Nutritional
Supplements*

Tabak's
HEALTH PRODUCTS
A Corporation

*Unprecedented
Customer
Service*

October 10, 2000

John B. Foret
Food and Drug Administration
Department of Health & Human Services
200 C Street SW
Washington, DC 20204



Dear Mr. Foret,

This is in response to your letter to Tabak's Health Products dated September 20, 2000.

Please find enclosed our "statement of responsible party" which applies to the previously submitted marketing materials.

In reference to your comments about our claims, here are my answers:

20/20 Caps

We do not believe this claim falls outside the allowed claims, since in the final rule under section 101.93 (g) (2) (iii) presbyopia (inability to change focus from near to far and vice versa) associated with aging would be an allowable claim. We believe macular degeneration associated with aging, likewise, is not a disease state, and therefore would be allowable.

However, in order not to argue the point, we have decided to remove this statement from our advertising.

Chromium Picolinate

We do not agree with you that "helps maintain normal blood sugar levels" falls outside of the scope of the rule, since no mention is made of treating diabetes or the symptoms of diabetes. I quote from the rule, "used as part of your diet to help maintain a healthy blood sugar level, the claim would be considered acceptable. Deleting the reference to the drug, insulin, would remove the implication that the dietary supplement is used to augment the insulin to treat, mitigate, prevent, or cure diabetes".

Therefore, unless you notify us of your reason why this statement is not appropriate, we will continue to use it.

ThinkCaps

"patients...who had moderate to severe cognitive decline"

We do not agree that this is a medical/disease claim because the product is advertising a normal decline in memory associated with aging.

However, in order not to argue the point we have decided to remove that statement from our advertising.

Heartshield

We do not agree with you that our advertising suggests that our product treats heart disease.

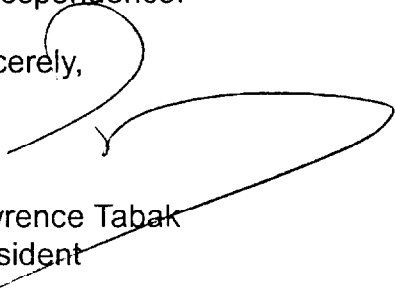
However, in order not to argue the point we will remove these statements for Heartshield from our advertising.

Arthritis Ease

These claims should not have been submitted since this product is a homeopathic over the counter medicine, not a dietary supplement.

Please, would you be kind enough to acknowledge receipt of this correspondence.

Sincerely,



Lawrence Tabak
President

P.S. The above referenced changes will be incorporated into our advertising materials at our earliest convenience, as soon as we re-print the literature.



Our Guiding Philosophy:
Superior, *Science-Based*
Nutritional Supplements

I, Lawrence Tabak, certify the accuracy of the information presented and contained in the notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

To the best of my knowledge and belief, I believe the above is true.

A handwritten signature of Lawrence Tabak, consisting of a large, stylized "L" followed by a series of loops and a final flourish.

10/11/2000

Lawrence Tabak,
President